

**REMARKS**

Reconsideration of the rejection or objection to all claims is respectfully requested in view of the above amendments and the following remarks.

***Specification Amendments***

The Examiner is thanked for calling attention to what is obviously a clerical error, *i.e.*, the recitation of "R<sup>6</sup>-NH<sub>2</sub>-" within the definition of the group R<sup>2</sup>. Unfortunately this error was propagated through the specification and claims. Clearly this is an obvious error and it is also immediately obvious what the correct version of this term should be, *i.e.*, "R<sup>6</sup>-NH-". The absence of an explicit "+" to indicate a positive charge immediately highlights that there is an error and if any doubt remained one only has to notice that the dependent claims clearly recite only neutral amino species and no positively charged ammonium compounds as the Examiner has noticed. Moreover, every single one of the fifty examples of the application possesses a neutral nitrogen atom at this position, as opposed to a positively charged ammonium group.

Accordingly the correction of this error in a manner that is consistent with the more specific recitation of such groups, including the exemplification, does not add new matter. Therefore the correction of this error throughout the specification and claims by the above amendments does not add new matter, and entry of these amendments is respectfully requested.

***Claim Amendments***

Claims 2, 5, 6, 11, 12 and 17-20 have been cancelled, and claims 1, 3, 4, 7-10 and 13-16 have been amended in the manner noted below:

Claim 1 has been narrowed in scope in order to expedite the prosecution of this application and to insure that the claims are entitled to benefit of the priority application filing date. In particular, the limitations of claims 2, 5 and 6 have been incorporated into claim 1 and additionally the recitation of "benzyl" has been removed from the definition of R<sup>4</sup>. Claim 1 now also correctly recites the term "R<sup>6</sup>-NH-" in the definition of R<sup>2</sup> as discussed above.

Claim 2 has been cancelled as being redundant in view of the amendment to claim 1.

Claim 3 has been amended to be dependent on claim 1 only and to correctly recite the term "R<sup>6</sup>-NH-" in the definition of R<sup>2</sup> as discussed above.

Claim 4 has been amended to be dependent on claim 1 only.

Claims 5 and 6 have been cancelled as being redundant in view of the amendment to claim 1.

Claim 7 has been amended to be dependent only on claim 1 only, and the definition of R<sup>4</sup> has been amended to be consistent with the amendments made to claim 1.

Claim 8 has been amended to remove two compounds that are no longer within the scope of amended claim 1.

Process-for-making claim 9 has been amended to more clearly recite that it is dependent on claim 1, to correctly recite the term "R<sup>6</sup>-NH-" in the definition of R<sup>2</sup>, and to change the subjective term "if necessary" to the more appropriate "optionally."

Claim 10 has been amended to update its dependency in view of the claim cancellations noted above.

Claims 11 and 12 have been cancelled as being in a "use" format not generally accepted under US practice.

Claims 13, 14 and 15 have been amended to convert them from a "use" format into a method format that is appropriate under US practice.

Claims 17-20 have been cancelled as being in a "use" format not generally accepted under US practice.

The above claim amendments are being made without abandonment or waiver of Applicants' right to prosecute any deleted subject matter in one or more continuing applications. It should be apparent from the above remarks that no new matter has been added by these amendments to the claims. Therefore, entry of these amendments is believed to be in order and is respectfully requested. Following entry of these amendments, claims 1, 3, 4, 7-10 and 13-16 remain pending in this application.

#### ***Claim Objections***

Claims 4-6 and 10-20 have been objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple

dependent claim. This objection has been obviated by the above amendments to the dependencies in a manner that has removed all improper multiple dependencies. Accordingly, withdrawal of this objection is respectfully requested.

***Claim Rejections - 35 USC § 112***

Claims 1-3 and 7-9 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for three enumerated reasons:

1. In claim 1, the Examiner notes that in the definition of  $R^2$ , the recitation " $R^6-NH_2-$ " is confusing in that this recitation shows that the nitrogen (N) in the amino group has four attachments, which would indicate that  $R^2$  is an ammonium group having a (+) charge. However the Examiner correctly notes that this is inconsistent with the specification, which does not disclose any such compounds having a tetravalent amino group.

2. The Examiner notes that claim 7 recites the limitation " $R^2$  is methylamino, allylamino, etc.," but correctly notes that there is insufficient antecedent basis for this limitation in claim 1 on which claim 7 is dependent.

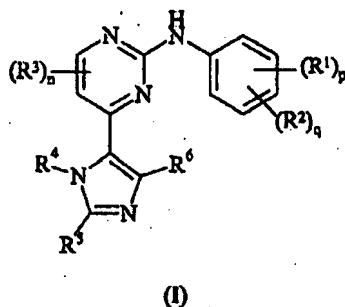
3. The Examiner notes that claim 8 recites species wherein  $R^2$  is cyclopropyl-NH-, but that there is insufficient antecedent basis for this limitation in the  $R^2$  definition in claim 1 which includes  $R^6-NH_2-$ , which indicates that such group will carry a charge as the nitrogen atom is shown to be tetravalent.

It is respectfully submitted that each of these grounds for the section 112 rejection has been obviated by the correction of the obvious clerical error as discussed above, correcting the erroneous " $R^6-NH_2-$ " to read " $R^6-NH-$ ." Accordingly, withdrawal of this section 112 rejection is respectfully requested.

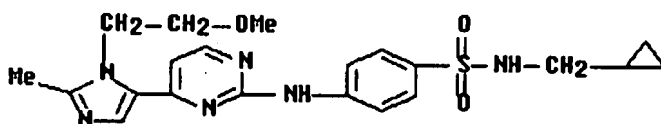
***Claim Rejections - 35 USC § 103***

Claims 1-3 and 7-9 have been rejected under 35 U.S.C. 103(a) as being obvious over Breault *et al.*, WO 02/20512 (hereinafter "WO '512"). The reference is said to generically teach imidazolo-5-yl-2-anilino-pyrimidine compounds having cell cycle inhibitory activity,

pointing specifically to formula (I) on page 2 of the reference:



wherein  $R^2$  is a group  $R^a-R^b$  - wherein  $R^b$  is  $-SO_2-NH-$  and  $R^a$  is as defined on page 3, and the  $R^4$  definition includes alkyl which may be substituted by  $R^d$  wherein  $R^d$  can be an alkoxy group. The reference is said to further disclose several compounds that fall within this subgenus noting, for example, the compound of Example 81:



The Examiner points out that the reference teaches  $R^4$  to be an alkoxy-alkyl group (*i.e.*, methoxyethyl in Example 81) whereas the present claims differ by reciting that  $R^4$  can be a 1-methoxyprop-2-yl group. The Examiner thus observes that the present claims differ from the reference by reciting a specific species or a more limited subgenus than the reference, and concludes that “it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole *i.e.*, as therapeutic agents [Action at page 4].”

This reference is first apparently applied under §102(a)/ §103(a). The Examiner notes that WO ‘512 was published March 14, 2002, which is *after* the March 9, 2002 priority date

claimed for this application, but justifies this §102(a)/ §103(a) based rejection on the assertion that the foreign priority document does not fully support the present claims. Specifically, it is pointed out that the priority document does not support the definition provided for R<sup>4</sup> in the present claims, which include the term "benzyl." Applicants believe that their claims as now amended are patentably distinguished from the disclosure of WO '512. Nevertheless, claims 1, 5 and 7 have also been amended to remove the term "benzyl" from the definition of R<sup>4</sup>, thereby giving all claims the benefit of the earlier filing date of the priority document. Therefore, this §102(a)/ §103(a) based rejection over WO '512 has been obviated.

This reference is also applied to a rejection based on §102(e)/ §103(a). However, the subject matter of WO '512 and the presently claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Therefore, the present claims fall within the §103(c) exception whereby WO '512 is not prior art to the present claims under §102(e).

It is therefore respectfully submitted that WO '512 is not prior art to the present claims under either §102(a) or §102(e), and therefore this obviousness rejection under §102(a)/ §103(a) and §102(e)/ §103(a) should be withdrawn.

***Claim Rejections - Obviousness-Type Double Patenting over US 6,969,714***

Claims 1-3 and 7-9 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,969,714 (herein after the '714" Patent"), which issued from the US National Stage application of the PCT application that published as WO '512 discussed above. The Examiner notes that although the conflicting claims are not identical, they are asserted not to be patentably distinct from each other because the instantly claimed compounds are structurally analogous to the reference compounds for the reasons summarized above with respect to the rejection under 35 U.S.C. 103.

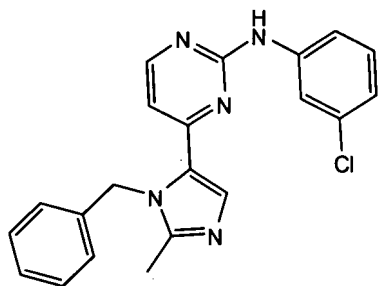
This ground for rejection is respectfully traversed.

In support of this rejection the Examiner refers back to his reasoning at pages 2-3 of the Action with respect to the rejection under 35 U.S.C. 103. Thus, it is asserted that the

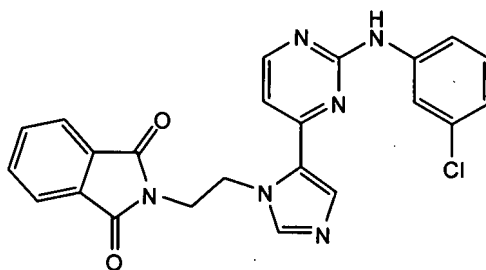
methoxyethyl group at R<sup>4</sup> that appears in Example 81 of WO '512 (and thus also the '714 Patent) teaches alkoxyalkyl groups generically, and that this group conflicts with the 1-methoxyprop-2-yl group that is claimed and exemplified in the subject application.

In hopes of expediting the prosecution of this Application to allowance (and without taking a position on the appropriateness of the Examiner's reasoning) Applicants have deleted the "1-methoxyprop-2-yl" group from the definition of R<sup>4</sup> in present claims 1 and 7, and for consistency have also deleted the two compounds listed in claim 8 that contain this group. Thus, as now amended, the R<sup>4</sup> group of the presently claimed compounds includes only "C<sub>3-6</sub>cycloalkyl, C<sub>3-6</sub>cycloalkylC<sub>1-4</sub>alkyl, or heterocyclyl." Note that the term "heterocyclyl" is specifically defined at page 4, lines 4-9 as being a "saturated monocyclic ring, linked via a ring carbon, which contains 3-6 atoms of which at least one atom is chosen from nitrogen, sulphur or oxygen and a ring sulphur atom may be optionally oxidised to form the S-oxide(s)." Examples of suitable values of the term "heterocyclyl" are also provided as guidance.

The '714 Patent is well exemplified, with some 165 Examples, but not one of those Examples includes a C<sub>3-6</sub>cycloalkyl group, a C<sub>3-6</sub>cycloalkylC<sub>1-4</sub>alkyl group or heterocyclyl group at the position of R<sup>4</sup>. Rather, the Examples of the '714 Patent generally teach that a small group is desirable at R<sup>4</sup>, specifically a simple methyl group in 104 of 165 examples, and some 144 of the 165 Examples of the '714 Patent (almost 90%) have an R<sup>4</sup> group that is a C<sub>2</sub> group *or smaller*. On the other hand, only two of the 165 Examples have *any* ring structure at the R<sup>4</sup> position, being Examples 7 and 10:



Example 7: 4-(1-Benzyl-2-methylimidazol-5-yl)-2-(3-chloroanilino)pyrimidine



Example 10: 2-(3-Chloroanilino)-4-[1-(2-phthalimidoethyl)imidazol-5-yl]pyrimidine

but neither of these ring structures is a “cycloalkyl” group or a “heterocyclyl” group (as defined above and in the specification), which is required by R<sup>4</sup> of the presently amended claims.<sup>1</sup> More specifically, not one of the 165 Examples of the ‘714 Patent has a cycloalkyl or heterocyclyl group within R<sup>4</sup> position. Clearly, then, the disclosure of the ‘714 Patent as a whole, teaches *away* from the placement of a cycloalkyl or heterocyclyl group at the position of R<sup>4</sup>.

Moreover, it must be recognized that an *obviousness-type double patenting* rejection must be based on a comparison of the present claims against *what is claimed* by the ‘714 Patent, not the entire disclosure. Although claim 1 of the ‘714 Patent appears to generally share the broad *generic* scope of its specification disclosure, when *specific* R<sup>4</sup> substituents are addressed in claim 12, these R<sup>4</sup> substituents are limited to “hydrogen, methyl, ethyl, isopropyl, 3-butenyl, benzyl, 2-phthalimidoethyl, 2-aminoethyl, 2-methoxyethyl, 2-acetamidoethyl, 2-mesylaminoethyl or 2,2,2-trifluoroethyl,” none of which come within the scope of the R<sup>4</sup> substituent required by the present claims. Additionally, each of the 10 *specific compounds* featured in claim 12 of the ‘714 Patent has a simple alkyl substituent at the R<sup>4</sup> position: a *methyl* group in five compounds, an *ethyl* group in four compounds, and an *isopropyl* group in one compound. Thus, none of the specifically claimed compounds in the ‘714 Patent comes even close to any of the “C<sub>3-6</sub>cycloalkyl, C<sub>3-6</sub>cycloalkylC<sub>1-4</sub>alkyl, or heterocyclyl” R<sup>4</sup> substituents required by the presently amended claims.

It is therefore respectfully submitted that the skilled person, when considering the claims of the ‘714 Patent, and particularly when considering them in light of the extensive exemplification, would be lead toward maintaining the clearly favored small, non-cyclic R<sup>4</sup> substituents as the most fruitful area for further exploration, and thus would be led *away* from the larger, cyclic C<sub>3-6</sub>cycloalkyl, C<sub>3-6</sub>cycloalkylC<sub>1-4</sub>alkyl substituents that are required at the R<sup>4</sup> position in the presently claimed compounds. Accordingly, *prima facie* obviousness of the present claims relative to the claims of the ‘714 Patent has *not* been established, and this obviousness-type double patenting rejection over the ‘714 Patent should be withdrawn.

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<sup>1</sup> These two compounds also do not come within the claimed scope of the present application because they lack the required S(O<sub>2</sub>)X substituent on the anilino ring.

***Provisional Obviousness-Type Double Patenting over  
Copending Applications No. 10/507,163 and No. 10/507,169***

Claims 1-3 and 7-9 have been *provisionally* rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/507,163, and also over claims 1-20 of copending Application No. 10/507,169. Both of these applications are currently pending before Examiner Rao with no allowed claims. Accordingly these provisional rejections remain provisional, and Applicant is not able to meaningfully address the rejections unless and until the claims are fixed in these application by allowance. Therefore, when the *provisional* obviousness-type double patenting rejection is the only remaining ground for rejection in this application (which it is believed should be the case following this Amendment and Response), then the present application should be allowed to issue.

***Information Disclosure Statement***

The Examiner's attention is respectfully called to the Supplemental Information Disclosure Statement being filed with this response, which also includes a table listing applications of Applicants' assignee that might be considered to involve technically related subject matter. To the extent that an application in the table has already granted as a US Patent, the US Patent number is listed therein and on the accompanying form PTO-1449, as well as the number of any corresponding published PCT application. With respect to those applications that are currently pending, the published US application and/or published PCT application is listed on the table and also in the accompanying form PTO-1449. A copy of any published PCT application so listed that has not previously been provided in this application is also being filed with the Supplemental Information Disclosure Statement.

Applicants wish to bring to the Examiner's attention the current status of the still-pending applications listed on that table as follows:

**US Application 10/507,081** is currently pending before Examiner Deepak R. Rao, and a non-final Action has been mailed, which has not yet been responded to.

**US Application 10/507,163** is currently pending before Examiner Deepak R. Rao, and a non-final Action has been mailed, which has not yet been responded to. This application has



been cited in a provisional obviousness-type double patenting rejection in the present application, as discussed above.

**US Application 10/507,169** is currently pending before Examiner Deepak R. Rao, and a non-final Action has been mailed, which has not yet been responded to. This application has been cited in a provisional obviousness-type double patenting rejection in the present application, as discussed above.

**US Application 10/556,561** is currently pending before Examiner Venkataraman Balasubramanian, and a non-final Action has been mailed, which has not yet been responded to.

**US Application 10/556,607** has been assigned to Examiner Deepak R. Rao, and a first Action is predicted to be mailed in 7 months from the present date.

**US Application 10/586,954** has been assigned to Examiner Deepak R. Rao, and a first Action is predicted to be mailed in 12 months from the present date.

**US Application 11/793,254** has not yet been assigned to a Group Art Unit or to an Examiner, and no prediction is available as of yet as to when a first Action might be mailed.

It is understood that the Examiner has full electronic access to each of these files. However, the undersigned would be happy to provide the Examiner with paper copies of any documents in these files upon requested, rather than inundating the US PTO and the Examiner at this time with unwanted paper.

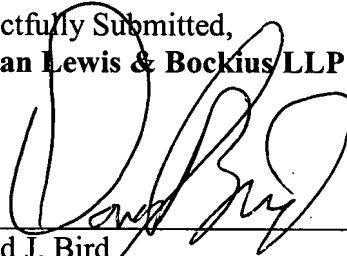
### ***Conclusion***

All ground for rejection having been addressed and, it is believed overcome, by the foregoing Amendments and Remarks, the allowance of all claims is respectfully requested together with the mailing of a Notice to that effect. However, if any issues remain outstanding after consideration of the above, it is respectfully requested that the Examiner telephone the undersigned to explore whether an expedited resolution might be obtained.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this

application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**



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